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80. (New) The energy transfer apparatus of claim 79 wherein said power supply is configured to deliver 10-15 Watts of power.

81. (New) The energy transfer apparatus of claim 70 wherein said power supply is configured to deliver energy for 5-10 seconds.

82. (New) The energy transfer apparatus of claim 81 wherein said power supply is configured to deliver energy in a temperature control mode.

## II. REMARKS

Claims 1-78 stand rejected on various grounds. These objections and rejections are addressed in the appropriate sections below. In particular, claim 1 has been amended to recite, amongst other things, "a temperature detecting element attached to one of said plurality of legs wherein said temperature element is in electrical communication with said leg." Support for this limitation can be found at the paragraph bridging pages 30 and 31 of the present application.

New claims 79 and 80 have also been added to recite certain features which have been found to be effective in treating lung tissue. This subject matter is supported in the application at page 39, lines 24-25. Likewise, new claims 81 and 82 are supported in the specification at, for example, page 39, lines 18-23. In view of the preceding amendments and the remarks made herein, the present application is believed to be in condition for allowance.

Please also find attached a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Marking To Show Changes Made".

**35 U.S.C. § 112, Second Paragraph**

Claims 18-43, 64, 68 and 69 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite as failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action provides:

> In claim 18 "said distal joint" lacks positive antecedent basis. In claims 26 and 64, "said temperature detecting element" lacks antecedent basis. Claim 38 is indefinite as the "other means" referred to is unclear. In claims 68 and 69 "said vision system" lacks positive antecedent basis.

With respect to claims 18, 26, 64, 68 and 69, Applicants have amended the claims on file to have proper antecedent basis. With respect to claim 38, Applicants have replaced "other means" with -- adhesive means--. This is supported in the application at for example, page 6 lines 1-3.

In view of the foregoing amendments and comments, it is respectfully requested that these rejections under §112, second paragraph, be withdrawn.

**Rejections Under 35 U.S.C. § 102**

Claims 1-4, 6, 11-13, 18, 20-22, 24, 25, 30, 38, 44, 45, 54-57, 65, 67, 73, 74, and 76:

Claims 1-4, 6, 11-13, 18, 20-22, 24, 25, 30, 38, 44, 45, 54-57, 65, 67, 73, 74, and 76 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 189329 to Fischell et al. ("Fischell").

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See* MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631(Fed. Cir. 1987)).

Fischell fails to describe each and every element required in claim 1. In particular, Fischell does not describe a temperature detecting element as recited in claim 1. Accordingly, Fischell fails to show all of the elements required in claim 1.

Based on the foregoing, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Fischell is respectfully requested. Since the other claims rejected based on Fischell are dependent on claim 1 and consequently include each of the features and limitations of claim 1, these claims are also not anticipated by Fischell. Reconsideration and withdrawal of the rejections of the claims based on Fischell are respectfully requested.

Claims 1-3, 6-8, 10-12, 14-16, 18, 19, 23, 35, 41, 54-57, 70, 71, 73, 74, and 76:

Claims 1-3, 6-8, 10-12, 14-16, 18, 19, 23, 35, 41, 54-57, 70, 71, 73, 74, and 76 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,799,749 to Spears.

Spears also does not describe a temperature detecting element as recited in claim 1. Accordingly, Spears fails to show all of the elements required in claim 1.

Based on the foregoing, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Spears is respectfully requested. Since the other claims rejected based on Spears are dependent on claim 1 and consequently include each of the features and limitations of claim 1, these claims are also not anticipated by Spears. Reconsideration and withdrawal of the rejections of the claims based on Spears are respectfully requested.

Claims 1, 3-6, 11, 13, 18-21, 30, 31, 37, 38, 54-61 and 70:

Claims 1, 3-6, 11, 13, 18-21, 30, 31, 37, 38, 54-61 and 70 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,725,525 to Kordis.

Kordis also does not disclose the temperature detecting element recited in claim 1. Withdrawal of the rejection of the claims based on Kordis is therefore requested.

Claims 1, 3-6, 8, 10-13, 18-21, 30, 38-40, 44-64, and 66:

Claims 1, 3-6, 8, 10-13, 18-21, 30, 38-40, 44-64, and 66 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,509,419 to Edwards et al. ("Edwards").

Edwards also does not disclose the temperature sensing element recited in claim 1. Withdrawal of the rejection of the claims based on Edwards is therefore requested.

Claims 74, 75 and 78:

Claims 74, 75 and 78 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,074,860 to Gregory et al. ("Gregory").

Gregory does not anticipate claims 74 and 75 for the reasons set forth above. With respect to claim 78, there is nothing in Gregory which discloses the claimed subject matter. Withdraw of the rejections of these claims is therefore requested.

Claims 1-11, 14-19, 21-23, 26-33, 38-40, 44, 45, 54-65, 70, 71 and 74:

Claims 1-11, 14-19, 21-23, 26-33, 38-40, 44, 45, 54-65, 70, 71 and 74 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,846,238 to Jackson et al. ("Jackson").

Jackson also does not anticipate the above recited claims because Jackson does not disclose a temperature detecting element in electrical communication with the leg of the expandable portion. In contrast, Jackson discloses use of a thermally conducting electrically insulated adhesive to bond the temperature sensor to a support structure. (See Figures 34-35 and col. 24, lines 33-34 of Jackson). The Jackson device is thus markedly different than that claimed by Applicants because Applicants' claimed structure has a temperature detecting element in electrical communication with a leg. This claim limitation is described in Applicants' specification at the paragraph bridging pages 30-31.

Based on the foregoing, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e) as being anticipated by Jackson are requested.

Nor is the above discussed limitation an obvious modification of the Jackson device. Jackson teaches the opposite of Applicants' claimed structure as recited in claim 1. Indeed,

Jackson specifically describes electrically insulating the temperature sensor elements 104 from the body 22. Nowhere in Jackson was a teaching or suggestion found to join the temperature detecting element and the leg such that the temperature detecting element is in electrical communication with the leg. Instead the device disclosed in Jackson electrically insulates the temperature sensor from the leg using an insulating adhesive. This is opposite to the structure recited in Applicants' claims. Accordingly, it is submitted that Jackson does not anticipate or render obvious Applicants' claims.

**Rejection Under 35 U.S.C. § 103(a)**

Claims 34, 36, 42, 43, 53, 68, 69, 72, 73 and 77 based on Jackson:

In view of the above remarks and amendments, reconsideration and withdrawal of the rejections of claims 34, 36, 42, 43, 53, 68, 69, 72 and 73 as being obvious is respectfully requested. With respect to claim 77, it has been amended to depend from claim 1 and, for the reasons set forth above, is believed to be in condition for allowance.

## III. CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 435712000921. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 18, 2001

Respectfully submitted,

By: _____

Richard R. Batt
Registration No. 43,485

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5616
Facsimile: (650) 494-0792

Attachment: Versions with marking to show changes made

Version With Marking To Show Changes Made

1. (Amended) An energy transfer apparatus for facilitating energy transfer into a mass of airway tissue, said apparatus sized to enter a bronchus or bronchiole of a human lung and comprising:

a flexible elongated body having a proximal portion and a distal portion and at least one lumen extending therebetween;

a distally located expandable portion of said elongated body, said expandable portion having a first state and a second state, wherein said second state is radially expanded from said elongated body;

a distal tip located distally of said expandable portion;

at least one energy transfer element at an exterior of said expandable portion, wherein each of said energy transfer elements is configured to contact a wall of the bronchus or bronchiole when said expandable portion is in said second state,

a proximal joint at an intersection of said distal portion and said expandable portion wherein said expandable portion comprises a plurality of legs, each of said legs having a first end extending from said proximal joint and a second end terminating at a distal joint, said distal joint being adjacent to said distal tip;

a temperature detecting element attached to one of said plurality of legs wherein said temperature detecting element is in electrical communication with said leg; and

a deployment member configured to move said expandable portion between said first and second state, said deployment member extending at least between said expandable portion and said proximal portion of said elongated body.

2. (Amended) The energy transfer apparatus of claim 1 wherein said temperature detecting element is attached to a surface of said leg [further comprising a temperature detecting element in proximity to said expandable portion].

3. The energy transfer apparatus of claim 1 wherein said energy transferring element each comprises a radio frequency electrode configured to heat the airway tissue by delivering radio frequency energy.

4. The energy transfer apparatus of claim 3 wherein said radio frequency generating electrode is monopolar.

5. The energy transfer apparatus of claim 3 wherein said radio frequency generating electrode is bipolar.

6. The energy transfer apparatus of claim 1 wherein said energy transferring element each comprises a resistively heated element configured to conductively heat the airway tissue.

7. The energy transfer apparatus of claim 6 wherein each of said resistively heated elements are conductively attached to said expandable portion.

8. The energy transfer apparatus of claim 6 wherein said resistively heated element uses AC current.

9. The energy transfer apparatus of claim 6 wherein said resistively heated element uses DC current.

10. The energy transfer apparatus of claim 6 wherein said resistively heated element uses RF energy.

11. The energy transfer apparatus of claim 1 wherein said energy transferring elements comprise at least one resistively heated element configured to heat the airway tissue and at least one radio frequency generating electrode configured to heat the airway tissue.

12. The energy transfer apparatus of claim 1 wherein a diameter of said expandable portion in said second state is less than 15 mm, and wherein said elongated body has a diameter less than said diameter of said expandable portion in said second state.

13. The energy transfer apparatus of claim 1 wherein said expandable portion comprises pre-shaped tines configured to expand upon advancement out a sheath and contract when withdrawn into said sheath, said pre-shaped tines also having a portion which is biased against the wall of the bronchus or bronchiole when said tines are expanded.

14. The energy transfer apparatus of claim 1 wherein said expandable portion comprises a balloon member.

15. The energy transfer apparatus of claim 14 further comprising a fluid which expands said balloon member into said second state.

16. The energy transfer apparatus of claim 15 further comprising a heat generating element within said balloon member, wherein said energy transfer element comprises a surface of said balloon member, and said fluid being configured to conduct heat from said heat generating element to said surface of said balloon member.

17. The energy transfer apparatus of claim 16 further comprising at least one RF electrode at an exterior of said balloon, said RF electrode configured to heat the airway tissue.

18. (Amended) The energy transfer apparatus of claim 1 wherein [further comprising a proximal joint at an intersection of said distal portion and said expandable portion, and wherein said expandable member comprises a plurality of legs, each of said legs having a first end extending from said proximal joint and a second end terminating at said distal joint, said distal joint being adjacent to said distal tip,] each of said legs having a center section substantially parallel to said elongated body and each of said legs being spaced around a circumference of said elongated body to form a basket.

19. (Amended) The energy transfer apparatus of claim 1[8] wherein each said basket leg has a circular cross section.

20. (Amended) The energy transfer apparatus of claim 1[8] wherein each said basket leg has a rectangular cross section.

21. (Amended) The energy transfer apparatus of claim 1[8] wherein at least of one of said legs comprises an electrically conductive material, and said leg functions as said energy transfer element.

22. The energy transfer apparatus of claim 21 wherein said basket legs comprise a stainless steel alloy.

23. (Amended) The energy transfer apparatus of claim 1[8] wherein said basket has a length from said proximal joint to said distal joint of less than 35 mm when said basket is in said first state.

24. (Amended) The energy transfer apparatus of claim 1[8] wherein said plurality of legs consists of four legs each spaced at approximately 90 degree intervals around said elongated body.

25. (Amended) The energy transfer apparatus of claim 1[8] wherein said plurality of legs consists of five legs each spaced at approximately 72 degree intervals around said elongated body.

26. (Amended) The energy transfer apparatus of claim 1[8] wherein said temperature detecting element is attached to an inside of a first leg of said plurality of single legs.

27. The energy transfer apparatus of claim 26 further comprising at least one additional temperature detecting element attached said plurality of legs.

28. (Amended) The energy transfer apparatus of claim 26 wherein said temperature detecting element is attached [in thermal communication to said first leg] by soldering, welding, or adhesive bonding[, or other adherents].

29. The energy transfer apparatus of claim 28 wherein said temperature detecting element is a thermocouple having a first and second leads joined separately to said first leg, each lead in electrical communication with said first leg.

30. (Amended) The energy transfer apparatus of claim 1[8] wherein a radio frequency electrode is attached to each leg of said basket.

31. The energy transfer apparatus of claim 30 wherein said radio frequency electrode is attached to each leg of said basket by a heat shrink fastener.

32. The energy transfer apparatus of claim 31 wherein said temperature detecting element is placed between at least one of said legs and said heat shrink fastener.

33. (Amended) The energy transfer apparatus of claim 1[8] wherein a resistively heated element is coiled around at least a portion of each legs.

34. The energy transfer apparatus of claim 33 wherein said temperature detecting element is placed between at least one of said legs and said resistively heated element.

35. (Amended) The energy transfer apparatus of claim 1[8] wherein a polymeric heating element is on at least a portion of each basket leg.

36. (Amended) The energy transfer apparatus of claim 1[8] wherein an electrically conductive paint covers at least a portion of each basket leg.

37 (Amended) The energy transfer apparatus of claim 1[8] wherein a printed flex circuit is on at least a portion of each basket leg.

38. (Amended) The energy transfer apparatus of claim 1[8] wherein said legs are joined in electrical communication at either proximal, distal, or both joints by soldering, welding, or adhesive [other] means.

39. The energy transfer apparatus of claim 38 wherein said distal joint further comprise an adhesive which fixedly attaches said ends of legs to said joint.

40. The energy transfer apparatus of claim 38 wherein either said proximal or distal joint not in electrical communication is adhesively bonded or thermoformed.

41. (Amended) The energy transfer apparatus of claim 1[8] wherein said elongated body comprises a plurality of basket leg lumens, wherein each of said ends of said basket legs is placed in each lumen.

42. (Amended) The energy transfer apparatus of claim 1[8] wherein said plurality of legs is formed from a single sheet.

43. The energy transfer apparatus of claim 42 wherein said sheet is a stainless steel material.

44. The energy transfer apparatus of claim 1 wherein said deployment member further comprises a sheath being slidably coupled and exterior to said elongated body and said expandable portion, and

wherein said expandable portion is resilient and upon advancement out of said sheath said expandable member self expand into said second state.

45. The energy transfer apparatus of claim 1 wherein said deployment member is force compensated to limit a force which said expandable member can apply to the airway while in said second expanded state.

46. The energy transfer apparatus of claim 1 wherein said deployment member further comprises a deflection limiting stop to limit a size of said second state of said expandable member.

47. The energy transfer apparatus of claim 1 wherein said deployment member comprises:

a handle adjacent to a proximal end of said elongated body;

a wire extending from said handle through said lumen of said elongated body and fixedly attached to said distal tip; and

and at least a first control member moveably attached to said handle.

48. The energy transfer apparatus of claim 47 wherein said elongated body is slidably attached to said handle;

said elongated body, said wire, and said distal tip are slidably moveable in distal and proximal directions; and further comprising

a stop configured to prevent distal movement of said wire beyond a deployment point, wherein beyond said deployment point distal movement of said elongated body against said non-moving distal tip causes said expansion member to expand to said second state.

49. The energy transfer apparatus of claim 48 further comprising a sheath, said sheath being slidably coupled and exterior to said elongated body and said expandable portion, wherein said expandable portion advances out of a distal end of said sheath to expand to said second state.

50. The energy transfer apparatus of claim 48 wherein said first control member is configured to advance said elongated body and said wire in distal and proximal directions.

51. The energy transfer apparatus of claim 50 further comprising a detent means for maintaining said elongated body distally of said deployment point.

52. (Amended) The energy transfer apparatus of claim 50 wherein said [controlmember] control member is configured to frictionally maintain said elongated body distally of said deployment point.

53. The energy transfer apparatus of claim 47 further comprising

a sheath external to and covering said elongated body and said expandable portion, said sheath extending from said distal tip to said proximal portion; and wherein

said handle is adjacent to a proximal end of said sheath, said sheath being slidably attached to said handle, said elongate body being rigidly attached to said handle;

said wire, and said distal tip are slidably moveable in distal and proximal directions;

said first control member being attached to said sheath, said first control member moveably secured to said handle, where distal movement of said first control member retracts said sheath distally on said elongate member uncovering said elongate member and said expandable portion; and

a second control member attached to said wire, said second control member moveably secured to said handle, where distal movement of said second control member retracts said distal tip and said expandable portion against said non-moving elongated member causing said expandable portion to radially expand into said second state.

54. The energy transfer apparatus of claim 1 wherein said elongated body has a wall reinforced with a polymeric or metallic member.

55. The energy transfer apparatus of claim 1 wherein said apparatus is sized to fit within a working channel of a bronchoscope.

56. The energy transfer apparatus of claim 55 wherein a diameter of said working channel of said bronchoscope is less than or equal to 2 mm.

57. The energy transfer apparatus of claim 1 wherein said flexible elongated member has a stiffness sufficient to pass through a working channel seal of a bronchoscope.

58. The energy transfer apparatus of claim 1 wherein said distal tip is configured to minimize gouging of the airway.

59. The energy transfer apparatus of claim 58 further comprising a redundant joint attaching said distal tip to said elongated body.

60. The energy transfer apparatus of claim 58 wherein said distal tip is sized to fit within a bronchoscope.

61. The energy transfer apparatus of claim 1 wherein said deployment member comprises a wire extending from said distal tip to said proximal portion, said wire being configured to provide a current to said energy transfer elements.

62. (Amended) The energy transfer apparatus of claim 1 wherein said deployment member comprises a wire extending from said distal tip to said proximal portion, said wire being configured to move said <u>expandable</u> [expansion] portion between said first and second states.

63. The energy transfer apparatus of claim 62 wherein said wire is also configured to provide a current to said energy transfer elements.

64. (Amended) The energy transfer apparatus of claim 62 wherein a [said] temperature detecting element is attached to a portion of said wire located within said expandable portion.

65. The energy transfer apparatus of claim 1 wherein a portion of said elongated body is radiopaque.

66. The energy transfer apparatus of claim 1 further comprising a steering member configured to deflect said distal tip in a desired direction.

67. (Amended) The energy transfer apparatus of claim 1 further comprising a vision system [member].

68. The energy transfer apparatus of claim 67 wherein said vision system comprises a fiber optic cable extending through said elongated body.

69. The energy transfer apparatus of claim 67 wherein said vision system comprises a CCD chip.

70. The energy transfer apparatus of claim 1 further comprising a power supply configured to deliver energy to through said energy transfer elements to the airway walls.

71. The energy transfer apparatus of claim 70 wherein said power supply is configured to stop delivery of energy if said temperature detecting element detects a predetermined maximum temperature.

72. The energy transfer apparatus of claim 70 wherein said power supply is configured to stop delivery of energy if a predetermined temperature change is not detected within a predetermined time.

73. The energy transfer apparatus of claim 1 wherein said apparatus is sterile.

74. A kit comprising

an energy transfer apparatus as recited in claim 1 for facilitating energy transfer into a mass of airway tissue, and

a generator configured to deliver energy to said energy transfer apparatus.

75. The kit of claim 74 further comprising a bronchoscope.

76. (Cancelled) The kit of claim 74 wherein said energy transfer apparatus is the apparatus of claim 1.

77. (Amended) The [An] energy transfer apparatus of claim 1 wherein [for facilitating energy transfer into a mass of airway tissue within a lung,] said energy transfer apparatus having been rendered sterile for the purposes of prevention of infection of the lung.

78. A modified lung having an artificially altered airway within the lung, said airway being artificially altered by transfer of energy to an airway wall such that the airway wall has an

attribute selected from the group consisting of a reduced ability to constrict, an increased airway diameter, an increase in resistance to plugging, and a decrease in resistance to airflow.

79. (New) The energy transfer apparatus of claim 70 wherein said power supply is configured to deliver energy for 3-5 seconds.

80. (New) The energy transfer apparatus of claim 79 wherein said power supply is configured to deliver 10-15 Watts of power.

81. (New) The energy transfer apparatus of claim 70 wherein said power supply is configured to deliver energy for 5-10 seconds.

82. (New) The energy transfer apparatus of claim 81 wherein said power supply is configured to deliver energy in a temperature controlled mode.

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